

peptides falling within the scope of the invention in the claims by using the language "consisting essentially of" to identify these peptides, as is properly done pursuant to M.P.E.P. 2111.03, and has been recognized by the Court of Appeals for the Federal Circuit. PPG Industries v. Guardian Industries, 156 F.3d 1351 (Fed. Cir. 1998).

In the prior Official Action, the Examiner had rejected the claims on the basis of the Burnham et al. U.S. Patent 5,955,078 and Hook European patent application 294,349. However, neither of these references disclose or suggest the specific claimed subject matter of the present invention, namely the generation of antibodies that inhibit binding of a fibronectin binding domain to fibronectin via the administration of a peptide from the fibronectin binding domain which does not itself bind to fibronectin. Moreover, the Examiner recognized that the cited references did not disclose or suggest the present invention in that no mention or suggestion is made in the Official Action that either cited reference disclosed or claimed the generation of antibodies specifically from peptides that did not bind to fibronectin.

To the contrary, the Examiner's rejection was based entirely on the assertion that Applicants' specification did not "include a clear indication of the basic and novel characteristics" of the claimed subject matter, and that the phrase "consisting essentially of" was considered open language. In this regard, it is clear that the cited Burnham reference does not disclose or suggest the present sequences, and indeed the sequences cited from the present claims are clearly not the sequences disclosed in the Burnham patent. In fact, Burnham makes no disclosure or suggestion of isolating any peptides using the claimed method. Further, as is noted in the enclosed

Declaration of Dr. Joseph Patti, Ph.D. ("Patti Dec."), although the claimed method involves peptides which are based upon epitopes from the fibronectin binding domain of fibronectin binding proteins, these peptides differ greatly from previously disclosed ones in that they do not themselves bind to fibronectin. See Patti Dec., § 3. Thus, although the Examiner asserted that the Burnham sequences were "100% identical" to the sequences recited in the present method claims, in fact these sequences are not disclosed or suggested in the Burnham patent despite the fact that they may have arisen from some of the same domains disclosed in Burnham.

Similarly, the Examiner asserted in the prior Official Action that the Hook European Patent contained the features of the present invention, but once again this could only have been based on the Examiner's view that the term "consisting essentially of" was considered open language. For example, the Examiner asserted that the antibody in the Hook patent was "100% identical" to the peptide of SEQ ID NO:3, but in fact this specific sequence is not disclosed or suggested in the Hook patent. Moreover, the Examiner's assertion that Hook disclosed the generation of an antibody that "inhibits [the binding of] said fibronectin binding protein to fibronectin" (citing page 8, lines 4-6 of the Hook patent) is in error since this is not what is disclosed. Indeed, the Hook patent at this passage merely states that "the fibronectin binding protein of this invention has been shown to form antibodies against a staphylococcal mastitis. . .", and not the inhibition of the binding of the fibronectin binding protein to fibronectin. Once again, it is clear that the Hook European patent does not disclose or suggest the claimed invention, and the only basis

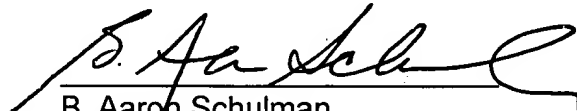
for the Examiner's rejection in light of this reference is the Examiner's improper interpretation of the term "consisting essentially of."

In short, the term "consisting essentially of" may be utilized in a case where, as here, the Applicants have made it clear in the specification what the novel and basic characteristic of the present invention is, namely the generation of an antibody to an isolated peptide of a fibronectin binding domain of a fibronectin binding protein that does not bind to fibronectin, as further explained in the attached Declaration of Dr. Patti. See Patti Dec., §§ 3-4. In light of this, the present claims can only be interpreted in such a manner that makes it clear that they are not disclosed or suggested in the cited Burnham and Hook references, and thus the Examiner's rejection on the basis of this cited prior art is respectfully traversed and should be withdrawn.

In light of the present amendments to the claims and the attachments submitted herewith, Applicants submit that the application in its present form is patentable over the references cited by the Examiner and is in condition for immediate allowance. Such action is earnestly solicited.

Respectfully submitted,

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ATTACHMENT A

Clean Replacement/New Claims

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Following herewith is a clean copy of the new claims.

54. (New) A method of generating an antibody that binds to a fibronectin binding domain of a fibronectin binding protein and inhibits binding of said fibronectin binding protein to fibronectin, comprising administering to a human or animal a pharmaceutical composition comprising an immunologically effective amount of a peptide of a fibronectin binding domain of a fibronectin binding protein that does not bind to fibronectin, wherein said peptide consists essentially of a peptide selected from the group consisting of amino acid sequences SEQ ID NOS:2-10, 13, 17-20, 54-61, 86, 87, 103 and 104.

55. (New) A method according to Claim 54 wherein said peptide that does not bind to fibronectin is a truncated peptide.

56. (New) A method according to Claim 54 wherein said peptide that does not bind to fibronectin is a mutated peptide.

57. (New) A method according to Claim 54 wherein said pharmaceutical composition is prepared by:

- a) contacting a candidate peptide with fibronectin under effective binding conditions and identifying a positive candidate peptide that does not bind to fibronectin; and
- b) dispersing said positive candidate peptide in a pharmaceutically acceptable diluent

58. (New) A method according to Claim 57 wherein a plurality of candidate peptides are contacted with fibronectin under effective binding conditions, and a positive candidate peptide that does not bind to fibronectin is identified.

59. (New) A method according to Claim 54 wherein the pharmaceutical composition is administered to a human or animal suspected of having, or at risk of developing, a microbial infection.